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09/801,486	03/08/2001	Alan H. Shikani	20355-PA	4743

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EXAMINER

PATEL, MITAL B

ART UNIT PAPER NUMBER

3761

DATE MAILED: 07/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/801,486

Applicant(s)

SHIKANI, ALAN H.

Examiner

Mital B. Patel

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "20" has been used to designate both band and adjusting means. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "22" has been used to designate single means, adjusting means and connector. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "24" has been used to designate both adjusting means and connecting means. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

4. Claims 14-17 are objected to because of the following informalities: The preamble of claims 15- 17 set forth the improvement. However, the preamble of claim 14 from which claims 15-17 depend from is directed to a tracheostomy tube device.

The Applicant needs to make the preamble consistent throughout the claims in order to maintain consistency and avoid any confusion. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4, 6, 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. There is a lack of antecedent basis for the following limitations:

- Claim 4, line 10, "the at least one of the bands"
- Claim 4, lines 6 and 7, "the neck piece"
- Claim 4, line 9, "the connected bands"
- Claim 6, lines 1-2, "the two bands"
- Claim 13, line 10, "the connecting means"
- Claim 14, line 1, "the improvement"

Correction is required.

***Claim Rejections - 35 USC § 101***

8. Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In claims 1-12, Applicant improperly positively recites a part of the human body.

9. In claims 1, 4, 7, 9, and 12, "a cannula inserted into the throat of the patient", should be rewritten as --a cannula **adapted to be** inserted into the throat of the patient--
10. In claims 1, 4, 10 and 12, "the bands encircle the neck of the patient", should be rewritten as --the bands adapted to encircle the neck of the patient--.
11. In claims 2, 5, 7, and 12, "a viscoelastic polymer which molds itself to the anatomy of the patient's neck", should be rewritten as --viscoelastic polymer which is adapted to mold itself to the anatomy of the patient's neck--.

Correction is required.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Tuman (US 5205832).
14. **As to claim 14**, Tuman teaches in a tracheostomy device, the improvement comprising a quick connect/quick disconnect strap **38a, 38b (See Fig.4)** with adjustability for easily fitting the device to a patient, and the strap being made from a relatively soft material for patient comfort.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wapner (US 4331144) in view of Tuman (US 5205832).

17. **As to claim 1**, Wapner teaches a tracheostomy tube adapted to be disposed on the neck of a patient comprising a cannula **14** inserted into the throat of the patient; a neck plate **18** having a center opening therein, the cannula being received in the center opening, the neck plate having two bands (See Fig. 2) formed thereon, the bands extending in opposite directions outwardly from the neck plate, each band having a respective end, the respective ends of the bands having Velcro means to connect and disconnect to one another such that the bands encircle the neck of the patient. Wapner fails to specifically teach the means for being rapidly releasably connected as set forth in the specification in view of the means plus function language set forth in the claim, in which case the means is a buckle type quick-release fastener. However, Tuman does teach a buckle type means for being rapidly releasably connected so that the device can be released quickly. Therefore, it would be obvious to one of ordinary skill in the art to replace the Velcro means of Wapner with the quick-release means of Tuman, so that

18. it is easier and quicker to connect and disconnect the bands from each other. It

should also be noted that Wapner fails to specifically teach the bands being formed

integrally. However, it would be obvious to one of ordinary skill in the art to make the bands integral so that it is more economical and easier to manufacture.

19. Claims 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wapner (US 4331144) in view of Tuman (US 5205832) further in view of Belfer et al (US 5918598).

20. **As to claim 2**, Wapner teaches a tracheostomy tube adapted to be disposed on the neck of a patient comprising a cannula **14** inserted into the throat of the patient; a neck plate **18** having a center opening therein, the cannula being received in the center opening, the neck plate having two bands (See Fig. 2) formed thereon, the bands extending in opposite directions outwardly from the neck plate, each band having a respective end, the respective ends of the bands having Velcro means to connect and disconnect to one another such that the bands encircle the neck of the patient. Wapner fails to specifically teach the means for being rapidly releasably connected as set forth in the specification in view of the means plus function language set forth in the claim, in which case the means is a buckle type quick-release fastener. However, Tuman does teach a buckle type means for being rapidly releasably connected so that the device can be released quickly. Therefore, it would be obvious to one of ordinary skill in the art to replace the Velcro means of Wapner with the quick-release means of Tuman, so that it is easier and quicker to connect and disconnect the bands from each other. It should also be noted that Wapner fails to specifically teach the bands being formed integrally. However, it would be obvious to one of ordinary skill in the art to make the bands integral so that it is more economical and easier to manufacture. Finally, the above

combination fails to teach the neck plate and the bands formed from a viscoelastic polymer. However, Belfer does teach the use of a viscoelastic polymer for fitting and sealing to the contours of the individual and being able to maintain the seal on the patient even when the patient is moving or when stretching, pressing, or shearing forces are applied. Therefore, it would be obvious to one of ordinary skill in the art to make the neck plate and bands of the viscoelastic polymer so that the neck plate and bands will not only form a proper seal on the patient but also will move with the patient without providing discomfort to the patient.

21. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wapner (US 4331144) in view of Tuman (US 5205832) further in view of Lane (US 5555569).

22. **As to claim 3**, Wapner teaches a tracheostomy tube adapted to be disposed on the neck of a patient comprising a cannula **14** inserted into the throat of the patient; a neck plate **18** having a center opening therein, the cannula being received in the center opening, the neck plate having two bands (See Fig. 2) formed thereon, the bands extending in opposite directions outwardly from the neck plate, each band having a respective end, the respective ends of the bands having Velcro means to connect and disconnect to one another such that the bands encircle the neck of the patient. Wapner fails to specifically teach the means for being rapidly releasably connected as set forth in the specification in view of the means plus function language set forth in the claim, in which case the means is a buckle type quick-release fastener. However, Tuman does teach a buckle type means for being rapidly releasably connected so that the device

can be released quickly. Therefore, it would be obvious to one of ordinary skill in the art to replace the Velcro means of Wapner with the quick-release means of Tuman, so that it is easier and quicker to connect and disconnect the bands from each other. It should also be noted that Wapner fails to specifically teach the bands being formed integrally. However, it would be obvious to one of ordinary skill in the art to make the bands integral so that it is more economical and easier to manufacture. Finally, the above combination fails to specifically teach an adjustment means to at least one of the bands such that the at least one of the bands may be shortened or lengthened for the comfort of the patient. However, Lane does teach the use of adjustment means to adjust or tighten the device on the wearer. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Wapner and Tuman to include adjustment means so that the device can be adjusted or tightened when in use.

23. **As to claim 4**, Wapner teaches a tracheostomy tube adapted to be disposed on the neck of a patient comprising a cannula **14** inserted into the throat of the patient; a neck plate **18** having a first end, an opposite second end, and a center opening therein, the cannula being received in the center opening, a first band and a second band, each band having respective first end and a second end, the first end of the first band being connected to the first end of the neck plate, the first end of the second band being connected to the second end of the neck plate (See Fig. 2) the respective ends of the bands having Velcro means to connect and disconnect to one another such that the bands encircle the neck of the patient. Wapner fails to specifically teach the means for being rapidly connecting and disconnecting the second end of the first band with the

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second end of the second band, as set forth in the specification in view of the means plus function language set forth in the claim, in which case the means is a buckle type quick-release fastener. However, Tuman does teach a buckle type means for rapidly connecting and disconnecting so that the device can be donned or released quickly. Therefore, it would be obvious to one of ordinary skill in the art to replace the Velcro means of Wapner with the quick-release means of Tuman, so that it is easier and quicker to connect and disconnect the bands from each other. Finally, the above combination fails to specifically teach an adjustment means to at least one of the bands such that the at least one of the bands may be shortened or lengthened for the comfort of the patient. However, Lane does teach the use of adjustment means to adjust or tighten the device on the wearer. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Wapner and Tuman to include adjustment means so that the device can be adjusted or tightened when in use.

24. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wapner, Tuman, and Lane as applied to claim 4 above, and further in view of Belfer.

25. **As to claim 5**, Wapner, Tuman, and Lane teach essentially all of the limitations except for wherein the bands are formed from a viscoelastic polymer. However, Belfer does teach the use of a viscoelastic polymer for fitting and sealing to the contours of the individual and being able to maintain the seal on the patient even when the patient is moving or when stretching, pressing, or shearing forces are applied. Therefore, it would be obvious to one of ordinary skill in the art to make the bands of the viscoelastic

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polymer so that the bands will not only form a proper seal on the patient but also will move with the patient without providing discomfort to the patient.

26. **As to claim 6**, the above combination teaches essentially all of the limitations except for wherein the neck plate is integral with the two bands forming a unitary member. However, it would be obvious to one of ordinary skill in the art to make the neck plate and the bands a unitary member so that it is more economical and easier to manufacture.

27. Claims 7-11 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wapner (US 4331144) in view of Belfer.

28. **As to claim 7**, Wapner teaches a tracheostomy tube adapted to be disposed on the neck of a patient comprising a cannula **14** inserted into the throat of the patient; a neck plate **18** having a first end, an opposite second end, and a center opening therein, the cannula being received in the center opening, a band **10** between the first end of the neck plate and the second end of the neck plate, the band to encircle the neck of the patient, having an adjustable length which may be shortened or lengthened for the comfort of the patient. Wapner fails to specifically teach the band being formed from a viscoelastic polymer. However, Belfer does teach the use of a viscoelastic polymer for fitting and sealing to the contours of the individual and being able to maintain the seal on the patient even when the patient is moving or when stretching, pressing, or shearing forces are applied. Therefore, it would be obvious to one of ordinary skill in the art to make the band of the viscoelastic polymer so that the band will not only form a proper

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seal on the patient but also will move with the patient without providing discomfort to the patient.

**29. As to claim 8**, the above combination teaches essentially all of the limitations except for wherein the neck plate is integral with the band forming a unitary member. However, it would be obvious to one of ordinary skill in the art to make the neck plate and the band a unitary member so that it is more economical and easier to manufacture.

**30. As to claim 9**, Wapner teaches a tracheostomy tube adapted to be disposed on the neck of a patient comprising a cannula **14** inserted into the throat of the patient; and a neck plate **18**. Wapner fails to specifically teach the neck plate being formed from a viscoelastic polymer. However, Belfer does teach the use of a viscoelastic polymer for fitting and sealing to the contours of the individual and being able to maintain the seal on the patient even when the patient is moving or when stretching, pressing, or shearing forces are applied. Therefore, it would be obvious to one of ordinary skill in the art to make the neck plate of the viscoelastic polymer so that the band will not only form a proper seal on the patient but also will move with the patient without providing discomfort to the patient.

**31. As to claim 10**, Wapner teaches essentially all of the limitations except for wherein the bands are formed from a viscoelastic polymer. However, Belfer does teach the use of a viscoelastic polymer for fitting and sealing to the contours of the individual and being able to maintain the seal on the patient even when the patient is moving or when stretching, pressing, or shearing forces are applied. Therefore, it would be

obvious to one of ordinary skill in the art to make the bands of the viscoelastic polymer so that the bands will not only form a proper seal on the patient but also will move with the patient without providing discomfort to the patient.

**32. As to claim 11**, the above combination teaches a tracheostomy tube further comprising an adjustment means (the Examiner considers the Velcro to be adjustment means) attached to at least one of the bands such that the at least one of the bands may be shortened or lengthened for the comfort of the patient.

**33. As to claim 15**, Wapner teaches essentially all of the limitations except for wherein the strap is made from a viscoelastic polymer. However, Belfer does teach the use of a viscoelastic polymer for fitting and sealing to the contours of the individual and being able to maintain the seal on the patient even when the patient is moving or when stretching, pressing, or shearing forces are applied. Therefore, it would be obvious to one of ordinary skill in the art to make the strap of the viscoelastic polymer so that the strap will not only form a proper seal on the patient but also will move with the patient without providing discomfort to the patient.

**34. As to claims 16 and 17**, Wapner teaches essentially all of the limitations except for wherein the neck plate is made from a viscoelastic polymer. However, Belfer does teach the use of a viscoelastic polymer for fitting and sealing to the contours of the individual and being able to maintain the seal on the patient even when the patient is moving or when stretching, pressing, or shearing forces are applied. Therefore, it would be obvious to one of ordinary skill in the art to make the neck plate of the viscoelastic polymer so that the neck plate will not only form a proper seal on the patient but also will

move with the patient without providing discomfort to the patient. Furthermore, Wapner fails to teach the neck plate being formed integrally with the strap. However, it would be obvious to one of ordinary skill in the art to make the neck plate integral with the strap so that it is more economical and easier to manufacture.

35. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wapner in view of Belfer in view of Tanum further in view of Lane.

36. **As to claims 12 and 13**, Wapner teaches a tracheostomy tube adapted to be disposed on the neck of a patient comprising a cannula **14** inserted into the throat of the patient; a neck plate **18** having a center opening therein, the cannula being received in the center opening, the neck plate having two bands formed thereon, the bands extending in opposite directions outwardly from the neck plate (See Fig. 2), the respective ends of the bands having Velcro means to connect and disconnect to one another such that the bands encircle the neck of the patient. Wapner fails to specifically teach the bands are formed from a viscoelastic polymer. However, Belfer does teach the use of a viscoelastic polymer for fitting and sealing to the contours of the individual and being able to maintain the seal on the patient even when the patient is moving or when stretching, pressing, or shearing forces are applied. Therefore, it would be obvious to one of ordinary skill in the art to make the bands of the viscoelastic polymer so that the bands will not only form a proper seal on the patient but also will move with the patient without providing discomfort to the patient. Wapner and Belfer fail to specifically teach the means for being rapidly connecting and disconnecting the second end of the first band with the second end of the second band, as set forth in the

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specification in view of the means plus function language set forth in the claim, in which case the means is a buckle type quick-release fastener. However, Tuman does teach a buckle type means for rapidly connecting and disconnecting so that the device can be donned or released quickly. Therefore, it would be obvious to one of ordinary skill in the art to replace the Velcro means of Wapner with the quick-release means of Tuman, so that it is easier and quicker to connect and disconnect the bands from each other.

Finally, the above combination fails to specifically teach an adjustment means to at least one of the bands such that the at least one of the bands may be shortened or lengthened for the comfort of the patient. However, Lane does teach the use of adjustment means to adjust or tighten the device on the wearer. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Wapner, Belfer, and Tuman to include adjustment means so that the device can be adjusted or tightened when in use. It should also be noted that Wapner fails to teach the bands being formed integrally thereon. However, it would be obvious to one of ordinary skill to make the bands integral so that it is more economical and easier to manufacture. With respect to claim 13, the method of attaching a tracheostomy tube on the neck of a patient is taught by using the device of Wapner with the modification taught by Tanum.

### ***Conclusion***

37. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5481763 and US 4378921.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Aaron Lewis can be reached on 703-308-0716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp  
June 30, 2002



DENNIS RUHL  
PRIMARY EXAMINER